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C O N F I D E N T I A L SECTION 01 OF 03 TAIPEI 002626

SIPDIS

STATE FOR EAP/RSP/TC, STATE PASS AIT/W AND USTR, USTR FOR
FREEMAN, WINEMAN, AND WINTERS, USDOC FOR
4431/ITA/MAC/AP/OPB/TAIWAN/MBMORGAN

E.O. 12958: DECL: 06/14/2015

TAGS: [ECON](#) [ETRD](#) [TW](#)

SUBJECT: DOH DODGES A POTENTIAL TRADE/HEALTHCARE CRISIS

REF: A. 04 TAIPEI 4021

[B](#). TAIPEI 2078

Classified By: AIT Director Douglas Paal. Reasons 1.4 b/d

[1](#)1. (C) Summary: With the June 21 medical device registration deadline fast approaching, Taiwan,s Department of Health (DOH) still has thousands of applications pending but has issued just over 200 licenses. Without licenses, manufacturers feared they would be prohibited from importing products (from medical scissors to chemotherapy treatments) into Taiwan after June 20. DOH staff blames late registrations, but its lack of clear requirements and manpower to process applications are the real culprits. DOH senior staff have been scrambling to find a way to avoid a healthcare and trade-related crisis, even suggesting manufacturers might help to process applications. After direct intervention from AIT, DOH told medical device manufacturers it would authorize a blanket extension of import permit validity, potentially ensuring that needed medical equipment can continue to be supplied to Taiwan patients for at least another six months. End Summary.

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Background: How Not to Implement a New Regulation
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[1](#)2. (U) Taiwan,s Department of Health (DOH) announced in 2004 that all medical device manufacturers would have to register their products by June 20, 2005 or face exclusion from the Taiwan market. However, registration requirements were not finalized and made public until December 31, 2004, leading to complaints from manufacturers that there was insufficient time to comply with the new registration regulations. DOH responded by guaranteeing medical device manufacturers that all applications received before April 5, 2005 would be reviewed and issued import licenses. However, it quickly became clear that DOH lacked the staff and expertise to process the thousands of applications (Johnson and Johnson submitted more than one thousand registration applications, other U.S. manufacturers each submitted several hundred.) Sub-contracting application processing to the Industrial Technology Research Institute (ITRI) and the Pharmaceutical Testing Bureau (PTB), rather than speeding the registration process, has resulted in inconsistent requirements and sometimes bizarre requests for additional documentation.

[1](#)3. (SBU) In May, the Director General of the Bureau of Pharmaceutical Affairs, Dr. Wang Hui-po (who has since resigned, reportedly for unrelated reasons), assured AIT that all products for which applications had been received would continue to be allowed in the Taiwan market (reftel B). However, AIT subsequently learned that DOH planned only to allow stocks already in Taiwan to be used. All imports would be barred until licenses were issued.

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DOH Oblivious to the Trade Problem
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[1](#)4. (SBU) AIT accompanied representatives of AmCham's Medical Device Committee June 10 to meet with DOH Counselor Hsiao Mei-ling to discuss how DOH could overcome the law-based restrictions and avoid barring imported medical devices. Hsiao had been meeting constantly for several days with DOH staff and manufacturers and was clearly engaged in finding practical ways to allow urgently needed and perishable products to enter Taiwan. AIT made it clear that barring imports of medical devices, most of which have already been used in Taiwan for many years, would lead not only a potential health care crisis, but would also needlessly create a serious trade problem that would have a negative effect on U.S.-Taiwan trade relations. AIT also raised the problem with Board of Foreign Trade staff, with BOFT Director General Huang Chih-peng on June 10, and with Ministry of Economic Affairs Deputy Minister Steve Chen on June 13.

[1](#)5. (C) Hsiao was obviously more comfortable dealing with the issue as an operational rather than a policy matter, constantly trying to turn the discussion to ways to ensure that patients have continued access to needed devices. She

suggested issuing a limited number of emergency import licenses for perishable products, and proposed ways to more efficiently process applications, including recommending that manufacturers assign staff to assist ITRI and PTB process applications in advance of the June 21 deadline. Manufacturers were asked to bear these costs, in addition to the already considerable sums spent to prepare application documents, reportedly averaging over US\$1000 per application, for items that have already been widely used in Taiwan for many years.

16. (C) Econoff welcomed DOH,s efforts to protect the welfare of Taiwan patients, but again reminded Hsiao that if American manufacturers of medical devices were unable to import products because of bureaucratic inefficiencies within DOH there would obviously be negative ramifications in the US/Taiwan trade dialogue, in addition to serious health concerns. Hsiao lamented that the DOH legal office had already advised that import licenses could not be legally extended beyond the June 20 deadline and was even arguing that products already in Taiwan warehouses should not be used until licenses had been granted. She asked manufacturers to share the blame, but Econoff reiterated that the problem originated with DOH,s inability to set clear requirements and assign sufficient staff to process applications and suggested that DOH find a way to extend import permits for as long as need to insure applications could be processed and licenses issued.

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Last Minute Efforts Lurch Forward
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17. (C) American Medical Device suppliers met with ITRI on June 13 at Hsiao's urging and were prepared to assign staff to assist ITRI and the PTB to process applications at their own expense. However, according to representatives from the AmCham medical devices committee, these initiatives were resisted by ITRI staff. Instead, ITRI and representatives from Abbott, BD, and Beckmen Coulter discussed previously agreed guidelines and ITRI assured participants that some licenses would be issued June 14.

18. (C) On June 14, DOH called a meeting with representatives of medical device manufacturing associations to discuss ways to overcome the import license requirement. In that meeting, DOH officials told manufacturers that DOH would publicly announce by Friday, June 17 a decision to extend current import regulations for six months in order to allow DOH additional time to process registration applications.

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Comment: Poor Management=Future Problems Likely
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19. (C) If it plays out as promised, the above proposal to extend import permits could temporarily resolve our trade related concerns as well as head off a potential healthcare crisis for Taiwan patients. However, this was a problem that could have been easily avoided. Taiwan,s DOH has again made obvious its shortage of mid-level management and leadership skills. The medical device registration requirement has been public knowledge for well over one year. Medical device manufacturers, while not enthusiastic about the new requirement, have been willing to comply. The Department of Health had time to consult with manufacturers to devise reasonable requirements and procedures, but failed to do so. When warned by manufacturers that the number of applications was likely to exceed the processing capability of DOH staff, senior leadership dismissed this concern as an attempt simply to avoid regulation.

110. (C) As the scope of the problem became obvious even to DOH, its frantic attempts to overcome legal and personnel challenges to resolve the issue have left manufacturers, hospitals, and us frustrated. The medical device registration process is just the latest example of DOH regulating itself into trouble through a lack of consultation, communication and clear requirements and then relying on senior leadership to cobble together a policy adjustment to save the day at the last moment. (See reftel A) If DOH issues the announcement to extend import regulations through December 2005 as promised, it will have successfully dodged both trade and healthcare problems for now. But even if DOH is able to narrowly avoid this crisis in the near term, without a serious effort to improve mid-level management, leadership skills, and a broader vision within DOH, it is almost certain that this type of episode will be repeated. End Comment.

PAAL